

PATENT APPLICATION COVER SHEET

DOCKET NO. 12032

07/28/98



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Transmitted herewith is the patent application of:

Inventor: **LEE M. MIDDLEMAN and WALTER R. PYKA**

For: **DEVICE FOR ANCHORING TUBULAR ELEMENT**

Enclosed are:

- ☒ Seven (7) Sheet(s) of drawings
- ☒ Specification and Claims
- ☒ Declaration and Power of Attorney
- ☒ Information Disclosure Statement and PTO Form 1449
- ☒ Assignment and Assignment Recordation Cover Sheet
- ☒ The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)
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TOTAL CLAIMS	23 - 20 =	3
INDEPENDENT CLAIMS	5 - 3 =	2
MULTIPLE DEPENDENT CLAIMS PRESENTED		

If the difference in Col. 1 is less than zero, enter "0" in Col. 2

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"EXPRESS MAIL" mailing label number EL057223019US

Date of Deposit July 28, 1998

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DEVICE FOR ANCHORING TUBULAR ELEMENT

by

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BACKGROUND

The present invention relates to an apparatus for anchoring a tubular element such as a catheter within a passageway in a mammalian body. In particular, the present invention relates to an anchoring device provided within a catheter that is operable to position and retain the tubular element in place within vessels, arteries, ducts, and channels within the mammalian body.

In various medical procedures in which a catheter is inserted into tubular shaped structures in the body, such as vessels, arteries, ducts, and channels, it is important to anchor the catheter for specific periods of time at a selected location. For example, a common medical procedure that utilizes catheters involves the measuring of certain characteristics of a patient's blood and the monitoring of the patient's blood on a continuous basis. Continuous monitoring is desirable to obtain real time monitoring of the patient's condition. Typically, various intravascular blood gas sensing devices are used to measure blood gas concentrations, including concentrations of oxygen, carbon dioxide, pH level, and the like. However, a challenging problem in the use of blood gas sensors is the difficulty in retaining the catheter in place within the vessel and the difficulty in stabilizing the blood gas sensors so as to obtain an accurate flow reading. For example, due to movement of the sensors, attempts to measure blood gas concentrations directly and continuously have resulted in inaccurate and erratic sensor values.

In addition, the difficulty in anchoring or retaining tubular elements in place within a body passageway, such as a blood vessel, also affects their use with transluminal ultrasonic sensors which can be used to obtain images of blood vessels. For example, it is important to minimize the movement of transluminal ultrasonic sensors within a body passageway such as a blood vessel in order to obtain high quality images of the blood vessel. Moreover, the difficulty in anchoring or

retaining tubular elements in place within a body passageway may also affect their use with drug delivery systems, drug dosing, ultrasound systems, and sampling of a body material or fluid.

Devices for positioning tubular elements such as catheters within the body are known. However, many of these devices are not designed to be reversibly removed or moved to another location, and many of these devices are not designed to position or anchor a catheter over a very short distance, i.e., less than 1 centimeter.

There are known devices for positioning a sensor device in an artery, as exemplified in U.S. Patent No. 5,265,606 to Kujawski. The disclosed device includes an introducer catheter formed in a zigzag pattern having successive bends alternating on opposite sides of the central axis of the catheter, such that when the catheter is placed in the patient's artery, the bends on the opposite sides of the central axis will engage the wall of the artery lumen thus tending to stabilize the catheter in the lumen. However, the device is not designed to anchor the catheter over a very short distance, as the device includes a probe constructed to be passed through the catheter shaft, and the distal end of the probe protrudes substantially beyond the distal outlet. Moreover, in certain embodiments, the tip of the probe may be pointed which creates the danger of puncturing the vessel wall.

Other known devices, such as disclosed in U.S. Patent No. 5,135,517 to McCoy, include at least two separate positioning elements comprised of shape memory alloys and used to position a core member within a passageway formed in a body. However, the device uses a power supply to activate the thermal shape memory metal. Use of a power supply increases the complexity and the cost. In addition, if the power supply in McCoy is turned off, the device does not necessarily contract back to its original shape by itself. Moreover, there is a danger of overheating the device, and there is the

time inconvenience of having to wait for the device to cool down so that it can be safely removed from the body without injury to vessels.

Thus, there is a need for a device that anchors or positions a tubular element such as a catheter in body passageways, such as vessels, arteries, ducts, and channels. In particular, there is a need for a device that is designed to be reversibly removable from one selected location to another and that is designed to anchor or position a catheter over a very short distance, i.e., less than 1 centimeter, and that is designed to aid in accurately positioning a catheter in body passageways. In addition, there is a need for a device that anchors or positions a catheter in place within a body passageway and stabilizes intravascular blood gas sensors (O_2 , CO_2 , pH, and the like), so as to obtain accurate flow readings or sensor values. Moreover, there is a need for a device that anchors or positions a catheter in place within a body passageway and that minimizes the movement of transluminal ultrasonic sensors in the body passageway, so as to obtain high quality images of the body passageway such as blood vessels, etc., and that also minimizes movement of tubular components used in drug delivery systems, ultrasound systems, and body sampling systems. There is also a need for a device that may comprise a pseudoelastic shape memory alloy material and that includes all of the advantages that such a material provides. Finally, there is a need for a device that is easy to manufacture and assemble, that requires no power supply, requires no external heating or body heating or cooling down, and that minimizes the potential for tissue damage or discomfort to a patient upon insertion, deployment, and removal of the device.

SUMMARY OF THE INVENTION

The present invention is directed to an apparatus for anchoring a tubular element such as a catheter within a passageway formed in a mammalian body, such as in a vessel, artery, duct, channel, or the like. The apparatus is particularly suitable for anchoring and retaining steerable catheters within blood vessels, stabilizing blood flow sensors accurately in the center of a blood vessel to obtain an accurate flow or sensor reading, minimizing the movement of transluminal ultrasonic sensors to obtain high quality images, and minimizing the movement of tubular components used in connection with drug delivery systems, ultrasound systems, and body sampling systems. In addition, the apparatus of the present invention is easy to manufacture and assemble, requires no power supply, requires no heating or cooling down, and minimizes the potential for tissue damage or discomfort to a patient upon insertion, deployment and removal of the device.

The present invention provides an apparatus for anchoring a tubular element within a passageway formed in a mammalian body. According to one aspect of the present invention, the apparatus comprises a tubular element, preferably a catheter, having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending therethrough. The outer lumen has a proximal end and a distal end. The apparatus further comprises deployment means positioned within the outer lumen and slidable with respect to the outer lumen. The deployment means has a proximal end and a distal end. The apparatus further comprises a plurality of resilient anchoring members coupled to the distal end of the deployment means and extending longitudinally beyond the distal end of the deployment means. Each anchoring member is reversibly movable by the deployment means between a first position and a second position. In the first position, at least a portion of each anchoring member is retracted within the outer lumen of the tubular element. In the second position,

at least a portion of each anchoring member is deployed exteriorly to the outer lumen of the tubular element, so as to engage an inner wall of the mammalian passageway and anchor the tubular element in a selected position within the passageway.

According to another aspect of the present invention, the outer lumen of the tubular element
5 may also include openings near the distal end of the outer lumen through which at least a portion of each anchoring member may be deployed so as to engage an inner wall of a mammalian passageway and anchor the tubular element in a selected position within the passageway.

According to the present invention, the deployment means may comprise a flexible, elongated,
10 hollow tubular inner lumen. The deployment means may also comprise a flexible, elongated, hollow tubular inner lumen having a movable guide wire positioned within the inner lumen, wherein the guide wire has a proximal end and a distal end, and the distal end of the guide wire is coupled to a cap member, and the cap member is further coupled to the anchoring members. The deployment means may also comprise a guide wire having a proximal end and a distal end and further having a collar member coupled to the distal end of the guide wire.

15 Preferably, the anchoring members are comprised of a pseudoelastic material such as a nickel titanium alloy. However, the anchoring members may also be comprised of a material such as spring steel. Preferably, the number of anchoring members is two, three or four. Each of the anchoring members comprises a first end portion and a second end portion. Preferably, the first end portion of each of the anchoring members is coupled to the distal end of the deployment means. In one version,
20 the second end portions of each of the anchoring members may be coupled to a cap member. In another version, the second end portions of each of the anchoring members may be coupled to a retaining ring.

The present invention also provides a method for anchoring a tubular element within a passageway formed in a mammalian body. The method comprises the steps of, providing the anchoring apparatus of the present invention in the various embodiments, positioning the apparatus at a selected location within the passageway, deploying at least a portion of the anchoring members of the apparatus against an inner wall within the passageway, and disengaging the anchoring members from the inner wall and retracting the anchoring members back into the tubular element.

DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the present invention will become better understood from the following description, appended claims, and accompanying drawings where:

FIG. 1 shows a side view of a first embodiment of the device of the present invention positioned within a body passageway with the anchoring members in a retracted position, and also showing in phantom the anchoring members being deployed;

FIG. 2a shows an enlarged transverse cross-sectional view taken along lines 2-2 of FIG. 1, wherein the anchoring members are mounted within the wall of the inner lumen;

FIG. 2b shows an alternate variation of the enlarged transverse cross-sectional view of FIG. 2a, wherein the anchoring members are attached to the inner wall of the inner lumen;

FIG. 3 shows a side view of the first embodiment of the device of the present invention positioned within a body passageway with the anchoring members in a deployed position;

FIG. 4 shows a side view of the first embodiment of the device of the present invention positioned within a body passageway with the anchoring members in a deployed position at a very short distance exterior to the tubular element;

FIG. 5 shows a variation of the deployment means of the first embodiment of the device of the present invention wherein the deployment means comprises a guide wire coupled to a collar member;

FIG. 6 shows a variation of the anchoring members of the first embodiment of the device of the present invention wherein the anchoring members are coupled to a cap member and are in a retracted position;

FIG. 7 shows a variation of the anchoring members of the first embodiment of the device of the present invention wherein the anchoring members are coupled to a cap member and are in a deployed position;

FIG. 8 shows a variation of the deployment means and anchoring members of the first embodiment of the device of the present invention wherein the deployment means comprises an inner lumen having a guide wire coupled to the anchoring members, and the anchoring members are in a retracted position;

FIG. 9 shows a variation of the deployment means and anchoring members of the first embodiment of the device of the present invention wherein the deployment means comprises an inner lumen having a guide wire coupled to the anchoring members, and the anchoring members are in a deployed position;

FIG. 10 shows a side view of a second embodiment of the device of the present invention positioned within a body passageway with the anchoring members in a retracted position and the outer lumen having openings;

FIG. 11 shows a side view of a second embodiment of the device of the present invention positioned within a body passageway with the anchoring members in a deployed position through the openings of the outer lumen;

FIG. 12 shows an enlarged transverse cross-sectional view taken along lines 12-12 of FIG.

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FIG. 13 shows a variation of the anchoring members of the second embodiment of the device of the present invention wherein the anchoring members are coupled to a retaining ring and at least a portion of the anchoring members are in a deployed position through the openings of the outer lumen;

FIG. 14 shows a top view of the openings of the second embodiment of the present invention having a rectangular-shaped configuration;

FIG. 15 shows a top of view of the openings of the second embodiment of the present invention having a diamond-shaped configuration;

FIG. 16 shows a cross-sectional view of a distal end of an anchoring member deployed against the wall of a passageway; and,

FIG. 17 shows a cross-sectional view of another version of a distal end of an anchoring member of the present invention deployed against the wall of a passageway.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to an apparatus for anchoring a tubular element such as a catheter within a passageway formed in a mammalian body, such as in a vessel, artery, duct, channel, or the like. The apparatus is particularly suitable for anchoring and retaining steerable catheters within blood vessels, stabilizing blood flow sensors accurately within a blood vessel to obtain an accurate flow or sensor reading, minimizing the movement of transluminal ultrasonic sensors to obtain high quality images, and minimizing the movement of tubular components used in connection with drug delivery systems, ultrasound systems, and body sampling systems. Moreover, the apparatus is particularly suitable for minimizing the potential for tissue damage or discomfort to a patient upon insertion, deployment, and removal of the apparatus.

FIGS. 1-9 show a first embodiment of the present invention including variations of certain features. FIG. 1 shows a side view of the first embodiment of the present invention wherein an anchoring apparatus 10 is positioned within a mammalian passageway 12 defined by an inner wall 14 having a first surface 16. Typically, the mammalian passageway may be a blood vessel, artery, duct or channel. The apparatus 10 comprises a tubular element 18 having a flexible, elongated, hollow tubular outer lumen 20 with a central longitudinal axis 22 extending therethrough. The outer lumen 20 has a proximal end 24 and a distal end 26, and an elongated bore 28 which extends between the proximal end 24 and the distal end 26. Preferably the outer lumen 20 is substantially centered within the mammalian passageway, i.e., vessel, artery, etc., with the central longitudinal axis 22 being disposed along the central longitudinal axis (not shown) of the body passageway. Preferably, the tubular element 18 is in the form of a catheter or other device configured to be maneuvered through body passageways. Preferably, the tubular element 18 is capable of bending during advancement of

the apparatus 10 in body passageways to enable varied positioning and placement of the apparatus 10. The tubular element 18 may be formed of a flexible polymeric material, such as polyethylene, polypropylene, or other suitable polymeric materials. The outer diameter of the outer lumen 20 varies depending on the size of the passageway in which the apparatus 10 is used. Typically, the outer lumen 20 has an outer diameter D1 in the range of about 1.0 mm (millimeters) to about 7.0 mm.

As shown in FIG. 1, the apparatus 10 further comprises deployment means 30 positioned within the outer lumen 20. The deployment means 30 may have varying configurations, all of the configurations having a proximal end and a distal end. An outer surface 32 of the deployment means 30 is slidably movable with respect to an inner surface 34 of the outer lumen 20.

As shown in FIGS. 1-4, in one variation of the deployment means 30, the deployment means 30 comprises a flexible, elongated, hollow tubular inner lumen 36 having a proximal end 38, a distal end 40, and an elongated bore 42 which extends between the proximal end 38 and the distal end 40. The inner lumen also has an inner wall 44. Because the inner lumen 36 is hollow, this enables liquids to be transported through the inner lumen to the passageway site. In addition, it enables devices, such as a transducer, to be inserted and used at the site. Preferably, the inner lumen 36 is substantially centered within the outer lumen 20 along the central longitudinal axis 22 of the outer lumen 20. The inner lumen 36 may be formed of a flexible polymeric material, such as polyethylene, polypropylene, or other suitable polymeric materials, or may be formed of a suitable metal. Typically, the inner lumen 36 has an outer diameter D2 in the range of about 0.7 mm (millimeters) to about 6.0 mm, the diameter D2 being sized and selected so that it is slidable within the selected outer lumen 20.

As shown in FIG. 5, in another variation of the deployment means 30, the deployment means 30 may comprise a flexible, elongated guide wire 46 having a proximal end 48 and a distal end 50

wherein the distal end 50 of the guide wire 46 is coupled to or attached to a collar member 52. The distal end 50 of the guide wire 46 may be V-shaped. Preferably, the guide wire is comprised of a suitable flexible metal or polymeric material. Preferably, the collar member 52 is comprised of a suitable polymeric material. The collar member 52 should be of a suitable length so as to allow an outer surface 54 of the collar member 52 to be slidably movable with respect to the inner surface 34 of the outer lumen 20, and so the collar member 52 does not get unnecessarily angled or wedged within the outer lumen 20.

As shown in FIGS. 8-9, another variation of the deployment means 30 is shown, and will be discussed in further detail in connection with the discussion of FIGS. 8-9 below.

As shown in FIG. 1 and other FIGS., the apparatus 10 further comprises a plurality of resilient anchoring members 56 coupled to the distal end of the deployment means 30 and extending longitudinally beyond the distal end of the deployment means 30. The anchoring members 56 are designed to anchor or position the tubular element 18 or catheter in place within a mammalian passageway. As shown in FIG. 1, the anchoring members are shown in a retracted position, and are also shown in phantom being deployed.

Preferably, the anchoring members 56 of the present invention are comprised of an elastic material, and in particular, a pseudoelastic material, such as a nickel titanium (NiTi) alloy. Other suitable pseudoelastic materials may include for example, binary nickel titanium, and nickel titanium containing alloys including elemental additions such as V, Fe, Nb, Co, and Zr. Other suitable pseudoelastic materials include copper-based alloys comprising Cu, Al, and Zn; Cu, Al and Ni; and Cu and Zn.

The term "elastic material" as used herein means a material that has spring-like properties, that is, it is capable of being deformed by an applied stress and then springing back or recovering to or toward its original unstressed shape or configuration when the stress is removed. The elastic material is preferably highly elastic. The material can be polymeric or metallic, or a combination of both. The use of metals such as shape memory alloys is preferred. Shape memory alloys that exhibit pseudoelasticity, in particular, superelasticity, are especially preferred. U.S. Patent No. 4,935,068 to Duerig teaches the fundamental principles of shape memory alloys, and is herein incorporated by reference. U.S. Patent No. 5,486,183 to Middleman et al. also includes a discussion of pseudoelasticity, and is herein incorporated by reference.

A pseudoelastic alloy is capable of being elastically deformed far beyond the elastic limits of conventional metals. When a shape memory alloy is used, it is preferably a nickel titanium based alloy, which may include additional elements which might affect the yield strength that is available from the alloy or the temperature at which particular desired pseudoelastic characteristics are obtained. It is believed that the superelastic property is achieved by phase transformation within the alloy, rather than by the dislocation movements which occur during the plastic deformation of ordinary metals. Shape memory alloys have a special feature which is beneficial for certain of the embodiments of the present invention.

The use of nickel titanium alloy in the manufacture of the anchoring members 56 provides several advantages. The use of a nickel titanium alloy ensures a force no greater than a predetermined value because of the non-linear nature of nickel titanium based alloy. Thus, even though vessel size may vary, the maximum force will not exceed a given value. As a superelastic shape memory alloy is increasingly deformed from its unconstrained shape, some of its austenitic phase changes into

stress-induced martensite. A stress/strain curve presents a plateau during this phase change. This means that while the alloy undergoes this phase change, it can deform greatly with only minimal increases in loading. Therefore, elements comprising superelastic shape memory alloys have a built-in safety feature. Just as the stress/strain curves of shape memory alloys present a plateau upon loading, they also present a plateau in the stress/strain curve upon unloading. Unloading occurs when an element made of superelastic shape memory alloy is permitted to revert from a significantly deformed shape toward its original unstressed shape. Because of the plateau, such an element can maintain an almost constant force during much of the unloading cycle until just before it is completely unloaded.

Another advantage in using a nickel titanium alloy in the manufacture of the anchoring members 56 is that a maximum force for a given deflection is provided because a material of thick cross-section can be used given the 4% to 8% deformation possible. In addition, the use of a nickel titanium alloy allows for a more dramatic change for anchoring in a short distance. For example, as shown in FIG. 4, the use of nickel titanium alloy allows the anchoring of the tubular element 18 within the mammalian passageway 12 by deployment of the anchoring members 56 over a very short distance and adjacent the inner wall 14 of the mammalian passageway 12. The distance may be in the range of less than 1 centimeter. Preferably, the distance is less than 5 mm (millimeters). Most preferably, the distance is 1 mm to 3 mm.

The use of pseudoelastic material for the anchoring members of the present invention may prevent excess force on the wall of the mammalian passageway due to the nature of the stress-strain plateau. After the pseudoelastic material is deformed a certain amount (strain), the force does not continue to increase.

In addition to the use of a pseudoelastic material for the anchoring members 56, the anchoring members 56 may also be comprised of a material such as spring steel or other suitable spring material. However, although spring steel is less expensive to use, it does not provide the same amount of constant force or change over a short distance as does a pseudoelastic material. When used in the anchoring apparatus of the present invention, neither the pseudoelastic material nor the spring steel require external heating, such as by an external heating device, or require heating by the body, and also do not require external cooling devices.

Preferably, the number of anchoring members in the device of the present invention is two, three, or four. An apparatus of the present invention having two anchoring members is easier to manufacture, and an apparatus of the present invention having four anchoring members adds greater stability. However, an apparatus of the present invention having three anchoring members is most preferred because the ability to position and anchor the tubular element is maximized. However, it is also contemplated that a greater number of anchoring members may also be used in the present invention.

Preferably, the anchoring members 56 are spaced apart from each other and spaced equidistance from each other about the circumference of the deployment means 30, both when retracted within the outer lumen 20 or deployed from the outer lumen 20. As shown in FIG. 1, each anchoring member 56 has a first end portion 58 coupled to the distal end of the deployment means and a second end portion 60. The shape of the anchoring members, especially the second end portion, may vary depending on the amount of contact that is desired by the anchoring members against the passageway surface and depending on the curvature of the passageway surface. For example, the anchoring members may be designed to have a substantially oval cross-section 62, as

shown in FIG. 16, to provide a greater surface area of contact when the anchoring member is in contact with the inner wall of the passageway. Further, the anchoring members may be designed to have a cross-sectional shape 64, as shown in FIG. 17, wherein the top portion in contact with the passageway is substantially flat to provide an even greater surface area of contact when the anchoring member is in contact with the inner wall of the passageway. It is desirable that the anchoring members, especially the second end portion of the anchoring members, be designed to provide a greater surface area of contact against the passageway, which, in turn, provides a greater anchoring force.

Preferably, the anchoring members are constructed to have a slight bend, so that when they are deployed from the outer lumen, the anchoring members bow outwardly with a spring-like motion against the inner wall of the passageway. Typically, each anchoring member has a length in the range of about 1.0 mm (millimeter) to about 10.0 mm and a diameter D3 in the range of about 0.2 mm to about 1.0 mm, depending on the size of the selected lumen.

Typically, the anchoring members are first manufactured as separate structures rather than as a unitary structure with the other components of the apparatus 10, and then they are assembled together. The anchoring members may be attached to the deployment means by various methods known in the art, depending on what material the anchoring members and deployment means are comprised of. If the anchoring members are comprised of a pseudoelastic material, such as nickel titanium, the anchoring members may be attached to the deployment means by welding or by soldering with tin-silver or tin-gold, and using an aggressive flux. In addition, the anchoring members may be press-fit, crimped, or swaged to create attachment to the deployment means. In addition, attachment with an epoxy may also be used. Occasionally, for low stress applications, the

pseudoelastic material may be laser welded, followed by a post-weld heat treatment to relieve stress at the joint. If the anchoring members are comprised of a spring steel material, the anchoring members may be attached to the deployment means by welding or by soldering.

If the inner lumen 36 is made of a polymeric material, the anchoring members may be attached to the deployment means by mounting the anchoring members within the wall of the deployment means. FIG. 2a shows an enlarged cross-sectional view taken along lines 2-2 of FIG. 1, wherein the first end portions 58 of the anchoring members 56 are mounted within the inner wall 44 of the inner lumen 36 at the distal end 40 of the inner lumen 36. This type of attachment of the anchoring members provides a strong and stable attachment. FIG. 2b shows an alternate variation of the enlarged transverse cross-sectional view of FIG. 2a, wherein the first end portions 58 of the anchoring members 56 are coupled to the surface of the inner wall 44 of the inner lumen 36 at the distal end 40 of the inner lumen 36.

As shown in FIGS. 6-7, a variation of the configuration of the anchoring members 56 is shown. The second end portions 60 of the anchoring members 56 are curved inwardly toward each other and coupled to a cap member 66. Preferably, the cap member 66 is comprised of a suitable polymeric material or suitable metal. With this configuration of the anchoring members 56, the tips or ends of the second end portions 60 of the anchoring members 56 do not contact the inner wall 14 of the mammalian passageway upon deployment of the anchoring members. FIG. 6 shows the anchoring members 56 in the retracted position. FIG. 7 shows the anchoring members 56 in the deployed position. The configuration shown in FIGS. 6-7 is preferred if it is desired that no loose ends or tips of the anchoring members be in contact with the wall of the mammalian passageway upon deployment. The configuration shown in FIG. 6-7 may also include a guide wire (not shown).

As shown in FIGS. 8-9, another variation of the anchoring members 56 and a variation of the deployment means 30 is shown. The deployment means 30 comprises a flexible, elongated, hollow tubular inner lumen 68 having a proximal end 70 and a distal end 72. A movable and flexible guide wire 74 is positioned within the inner lumen 68. The guide wire 74 has a proximal end 76 and a distal end 78. The diameter of the inner lumen 68 may be significantly smaller than the outer lumen 20 providing ease of movement of the guide wire 74 and inner lumen 68 with respect to the outer lumen 20. The distal end 78 of the guide wire 74 extends beyond the distal end 72 of the inner lumen 68 and is coupled to a cap 80. The cap 80 may be comprised of a suitable polymeric material or metal. Preferably the cap 80 is substantially cylindrical in shape. The second end portions 60 of the anchoring members 56 may also be curved inwardly toward each other and coupled to the cap element 80 via crimping, soldering or other conventional means of attachment. In use, the guide wire 74 may preferably be moved independently of the inner lumen 68 and the anchoring members 56. Upon deployment, the anchoring members 56 may or may not spring out laterally when released from the constraint of the outer lumen. However, when the guide wire 74 is pulled toward the proximal end of the outer lumen, the anchoring members 56 are pushed outwardly and the guide wire 74 adds additional bow to the shape of the anchoring members 56. FIG. 8 shows the anchoring members 56 in the retracted position. FIG. 9 shows the anchoring members 56 in the deployed position.

Once the tubular element 18 or catheter is positioned at a desired location within the passageway 12 in the mammalian body, as shown in FIGS. 1-9, the anchoring members 56 may be partially or completely reversibly deployed and retracted from an opening 82 at the distal end 26 of the outer lumen 20. The anchoring members 56 may be movable between a first position and a second position. In the first position, at least a portion of the anchoring members 56 are in a retracted

position within the interior of the outer lumen 20. As shown in FIG. 1, the anchoring members 56 are shown in a retracted position and also shown in phantom in a partially deployed position. In the embodiment shown in FIGS. 1-5, the anchoring members are separate from each other, and preferably, in both the first position and the second position, the anchoring members are spaced apart from each other about the distal end of the inner lumen.

In the second position, at least a portion of the anchoring members 56 may be partially or completely deployed by the deployment means 30 exteriorly to the outer lumen 20, so that the second end portions 60 of the anchoring members 56 bow out or extend with a spring action laterally beyond the distal end opening 82 and engage the inner wall 14 of the mammalian passageway 12 and anchor or substantially anchor the tubular element 18 in a selected position within the passageway. Should a user wish to relocate the tubular element 18 to another location in the body, the anchoring members 56 may be retracted from the second position back to the first position, that is, the second end portions 60 of the anchoring members 56 may be disengaged from the inner wall 14 of the mammalian passageway 12 and may be retracted back through the distal end opening 82 of the outer lumen 20. The anchoring members 56 may be deployed over a normal distance within the mammalian passageway, or as shown in FIG. 4, the anchoring members 56 may be deployed over a very short distance, such as less than 1 centimeter, within the mammalian passageway.

Upon actuation, the deployment means 30 reversibly deploys and retracts the anchoring members 56 through the opening 82 in the distal end 26 of the outer lumen 20. The movement, deployment, and retraction of the anchoring members 56 is caused by movement of the deployment means 30 with respect to the outer lumen 20, such as by pushing the deployment means 30 forward from the proximal end 24 of the outer lumen 20 toward the distal end 26 of the outer lumen 20.

Known devices may be attached to the proximal end of the deployment means to cause movement of the deployment means with respect to the outer lumen. Such known devices (not shown) may include a plunger type mechanism, a lever type mechanism, a screw type mechanism, or other suitable mechanism known in the art, that are operated by the user of the apparatus to create the reversible movement of deployment or retraction. When in the retracted position, the entire apparatus may be moved or removed to a selected location.

FIGS. 10-13 show a second embodiment of the apparatus of the present invention. As shown in FIG. 10, the outer lumen 20 of anchoring apparatus 10 has a plurality of cut openings 84 located near the distal end 26 of the outer lumen 20. With this embodiment, the number of openings 84 should preferably correspond to the number of anchoring members 56. Preferably, the openings 84 are rectangular in shape with curved or slightly curved edges, as shown in FIG. 14, or are diamond in shape with curved or slightly curved edges, as shown in FIG. 15. Preferably, the openings 84 are spaced equidistance from each other about the circumference of the outer lumen 20. The dimensions of the openings 84 depend on the dimension of the tubular element 18 selected. However, preferably, the size of the openings 84 are in the range of about 0.5 cm (centimeter) to about 2.0 cm in length.

As shown in FIG. 10, resilient anchoring members 56 are in a retracted position within the outer lumen 20. Preferably, the anchoring members 56 in this aspect of the present invention are comprised of a pseudoelastic material or spring steel. In the retracted position, the anchoring members 56 are adjacent to the inner surface wall 34 of the outer lumen 20.

As shown in FIG. 11, the anchoring members 56 are deployed by deployment means 30 through the openings 84, so that the anchoring members 56 extend with a spring action laterally through the openings 84 and engage the inner wall 14 of the mammalian passageway 12, thereby

anchoring the apparatus 10 in a selected position within the passageway. Upon retraction of the anchoring members 56 by the deployment means 30, the second end portions 60 of the anchoring members 56 are disengaged from the inner wall 14 of the mammalian passageway 12 and are retracted back through the openings 84. The deployment means 30 is coupled to the first end portions 58 of the anchoring members 56 and, upon actuation, the deployment means moves the anchoring members 56 a selected distance along the outer lumen 20 and reversibly deploys and retracts the second end portions 60 of the anchoring members 56 through the openings 84. FIG. 12 shows an enlarged transversed cross-sectional view taken along lines 12-12 of FIG. 11.

As shown in FIG. 13, the anchoring members 56 may be formed in another configuration. The second end portions 60 of the anchoring members 56 may be coupled to a retaining ring 86. The retaining ring 86 may be comprised of a suitable polymeric material or a suitable metal. The retaining ring 86 is moved with movement of the inner lumen 36 and guides the anchoring members 56. With this design, when the inner lumen 36 is moved forward toward the distal end of the outer lumen 20, at least a portion of each of the anchoring members 56 extends outwardly through the openings 84 and deploy to their memory shape. The configuration shown in FIG. 13 may also include a guide wire (not shown).

The present invention also provides a method for anchoring a tubular element within a passageway formed in a mammalian body. The method comprises the steps of providing the anchoring apparatus of the present invention, positioning the apparatus at a selected location within the passageway, deploying at least a portion of the anchoring members of the apparatus against an inner wall within the passageway, and disengaging the anchoring members from the inner wall and retracting the anchoring members back into the tubular element.

Although the present invention has been described in considerable detail with reference to certain preferred embodiments thereof, other embodiments are possible. It is intended to cover all modifications, alternatives and equivalents which may fall within the spirit and scope of the invention as defined in the appended claims.

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CLAIMS

What is claimed is:

1. An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the apparatus comprising:

5 a) a tubular element having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending therethrough, the outer lumen having a proximal end and a distal end;

b) deployment means positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means having a proximal end and a distal end; and,

10 c) a plurality of resilient anchoring members coupled to the distal end of the deployment means and extending longitudinally beyond the distal end of the deployment means, each anchoring member being reversibly movable by the deployment means between a first position and a second position, wherein in the first position, at least a portion of each anchoring member is retracted within the outer lumen of the tubular element, and wherein in the second position, at least a portion of each anchoring member is deployed exteriorly to the outer lumen of the tubular element, so as to engage
15 an inner wall of the mammalian passageway and anchor the tubular element in a selected position within the passageway.

2. The apparatus of claim 1 wherein the tubular element is a catheter.

3. The apparatus of claim 1 wherein the outer lumen has openings near the distal end of the outer lumen through which at least a portion of each anchoring member is deployed so as to engage the inner wall of the mammalian passageway and anchor the tubular element in the selected position.

5 4. The apparatus of claim 1 wherein the deployment means comprises a flexible, elongated, hollow tubular inner lumen.

5. The apparatus of claim 4 wherein the deployment means further comprises a guide wire.

10 6. The apparatus of claim 4 wherein a movable guide wire having a proximal end and a distal end is positioned within the inner lumen, and further wherein the distal end of the guide wire is coupled to a cap member, the cap member further being coupled to the anchoring members.

15 7. The apparatus of claim 1 wherein the deployment means comprises an elongated guide wire having a proximal end and a distal end, and further having a collar member coupled to the distal end of the guide wire.

8. The apparatus of claim 1 wherein the anchoring members are comprised of a pseudoelastic material.

20 9. The apparatus of claim 8 wherein the pseudoelastic material is a nickel titanium alloy.

10. The apparatus of claim 1 wherein the anchoring members are comprised of spring steel.

11. The apparatus of claim 1 having two anchoring members.

5 12. The apparatus of claim 1 having three anchoring members.

13. The apparatus of claim 1 wherein the anchoring members have a first end portion coupled to the distal end of the deployment means, and a second end portion coupled to a cap element.

10 14. An apparatus for anchoring a catheter within a passageway formed in a mammalian body, the apparatus comprising:

a) a catheter having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending therethrough, the outer lumen having a proximal end and a distal end;

15 b) deployment means positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means having a proximal end and a distal end; and,

c) a plurality of resilient anchoring members comprised of a pseudoelastic material and coupled to the distal end of the deployment means and extending longitudinally beyond the distal end of the deployment means, each anchoring member being reversibly movable by the deployment means between a first position and a second position, wherein in the first position, at least a portion of each anchoring member is retracted within the outer lumen of the catheter, and wherein in the second position, at least a portion of each of the anchoring members is deployed exteriorly to the outer lumen

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of the catheter, so as to engage an inner wall of the mammalian passageway and anchor the catheter in a selected position within the passageway.

15. The apparatus of claim 14 wherein the pseudoelastic material is a nickel titanium alloy.

16. An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the apparatus comprising:

a) a tubular element having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending therethrough, the outer lumen having a proximal end and a distal end;

b) a plurality of openings located near the distal end of the outer lumen;

c) deployment means positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means having a proximal end and a distal end; and,

d) a plurality of resilient anchoring members coupled to the distal end of the deployment means and extending longitudinally beyond the distal end of the deployment means, each anchoring member being reversibly movable by the deployment means between a first position and a second position, wherein in the first position, at least a portion of each anchoring member is retracted within the outer lumen of the tubular element, and wherein in the second position, at least a portion of each of the anchoring members is deployed through the openings exteriorly to the outer lumen of the tubular element, so as to engage an inner wall of the mammalian passageway and anchor the tubular element in a selected position within the passageway.

17. The apparatus of claim 16 wherein the anchoring members are comprised of a pseudoelastic material.

18. The apparatus of claim 17 wherein the pseudoelastic material is a nickel titanium alloy.

5

19. The apparatus of claim 16 wherein the anchoring members are comprised of spring steel.

20. The apparatus of claim 16 wherein the anchoring members have a first end portion coupled to the distal end of the deployment means and a second end portion coupled to a retaining ring.

10

21. The apparatus of claim 20 further comprising a guide wire.

22. A method for anchoring a tubular element within a passageway formed in a mammalian body, the method comprising the steps of:

15

- a) providing the apparatus of claim 1;
- b) positioning the apparatus of claim 1 at a selected location within the passageway;
- c) deploying at least a portion of anchoring members of the apparatus of claim 1 against an inner wall within the passageway; and,
- d) disengaging the anchoring members from the inner wall and retracting the anchoring members back into the tubular element.

20

- [illegible]

ABSTRACT

10 3634-072898

5 The present invention is directed to an apparatus for anchoring a tubular element, preferably in the form of a catheter, within a passageway formed in a mammalian body, such as in a vessel, artery, duct, channel, or the like. The apparatus comprises a tubular element having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending therethrough, the outer lumen having a proximal end and a distal end. The apparatus further comprises deployment means positioned within the outer lumen and slidable with respect to the outer lumen. The deployment means has a proximal end and a distal end. The apparatus further comprises a plurality of resilient anchoring members preferably formed of a pseudoelastic material. The anchoring members are coupled to the distal end of the deployment means and extend longitudinally beyond the distal end of the deployment means. Each anchoring member is reversibly movable by the deployment means between a first position and a second position. In the first position, at least a portion of each anchoring member is retracted within the outer lumen of the tubular element. In the second position, at least a portion of each of the anchoring members is deployed exteriorly to the outer lumen of the tubular element, so as to engage an inner wall of the mammalian passageway and anchor the tubular element in a selected position within the passageway.

15

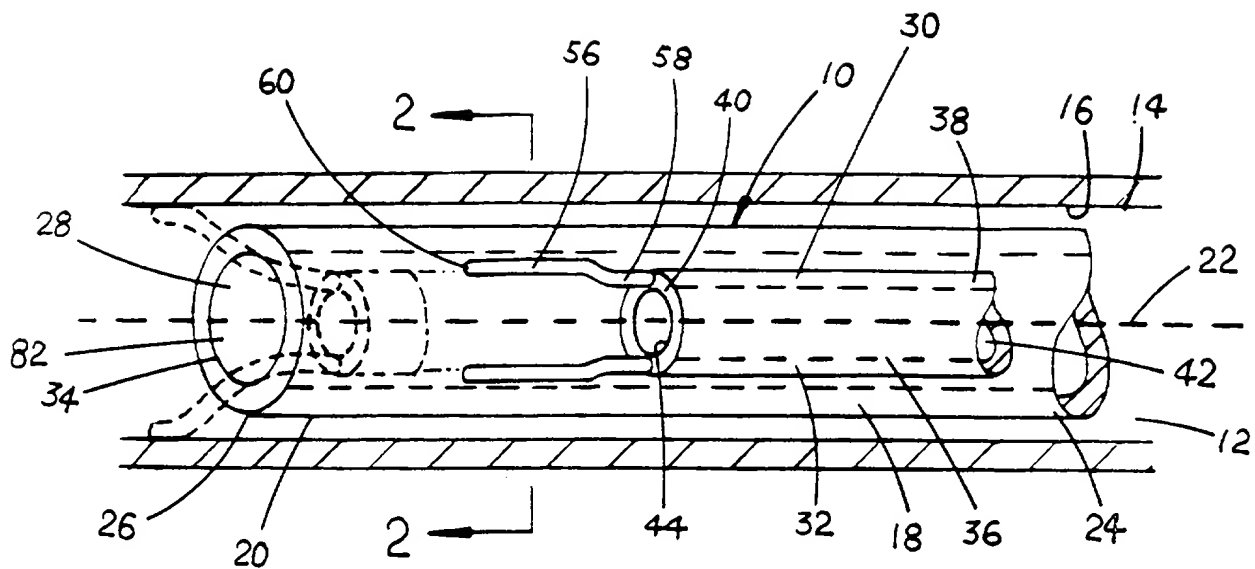


FIG. 1

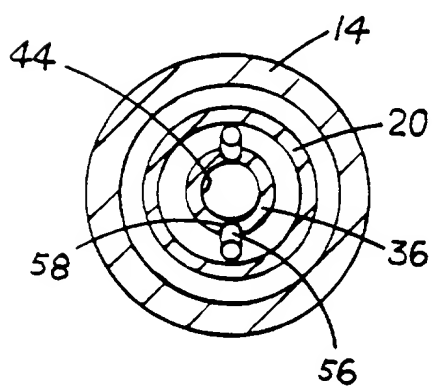


FIG. 2a

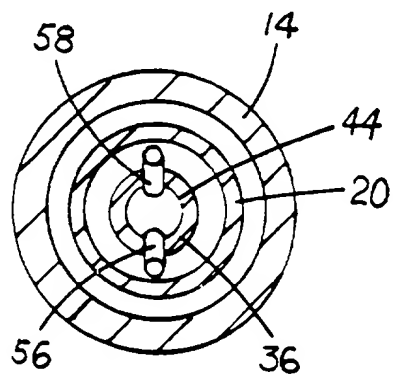
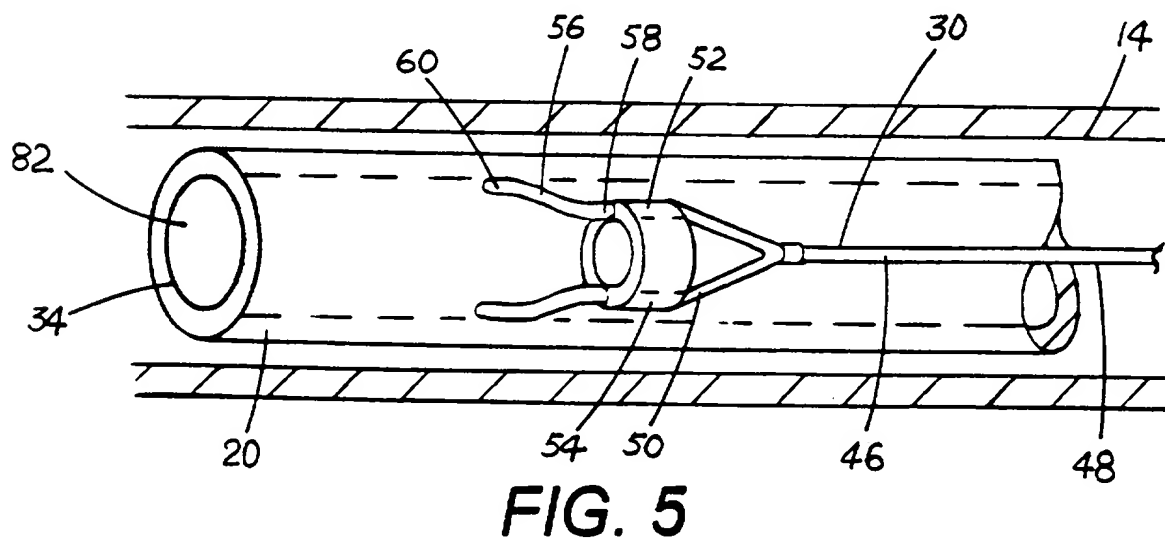
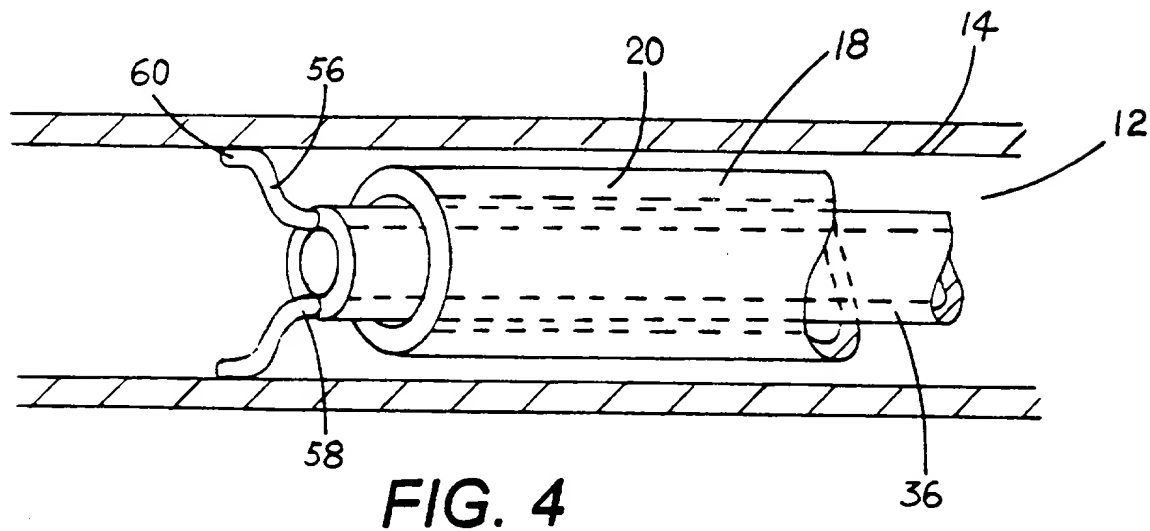
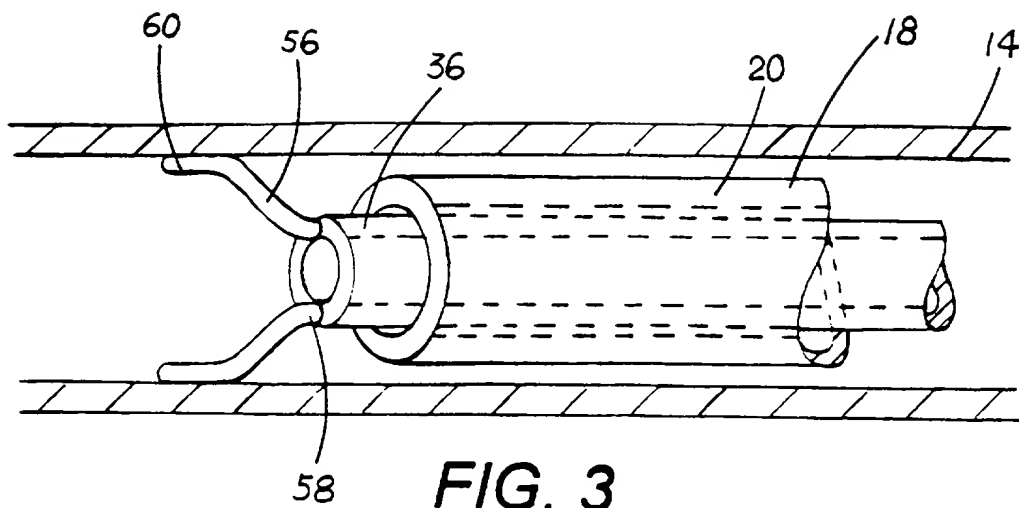


FIG. 2b



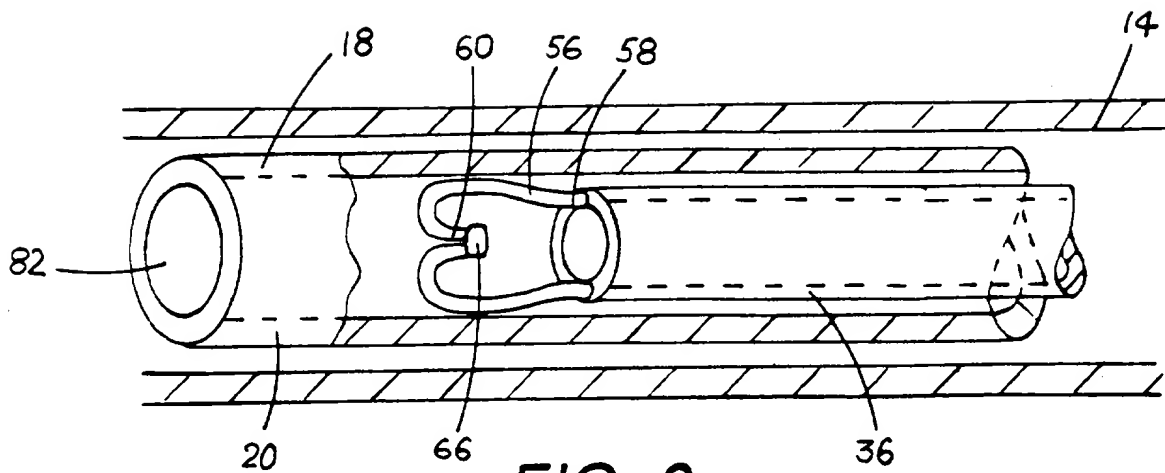


FIG. 6

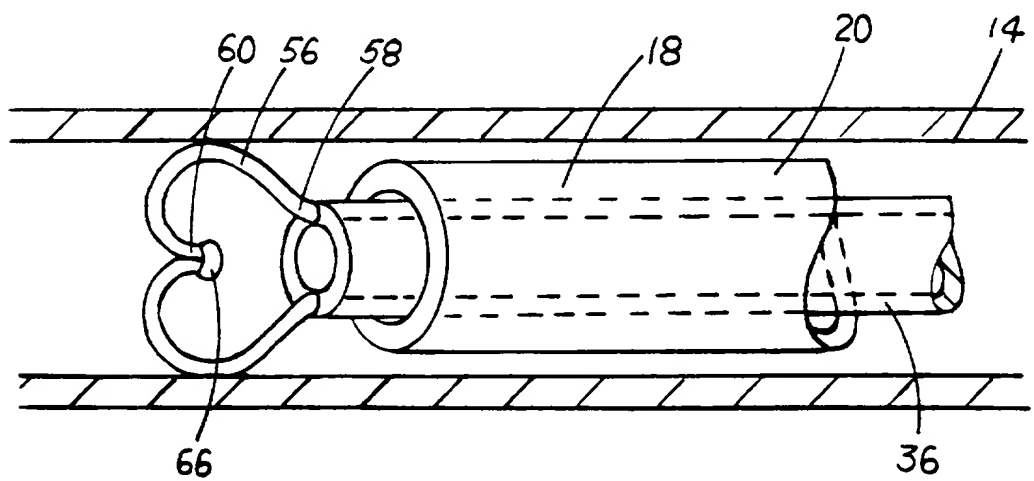


FIG. 7

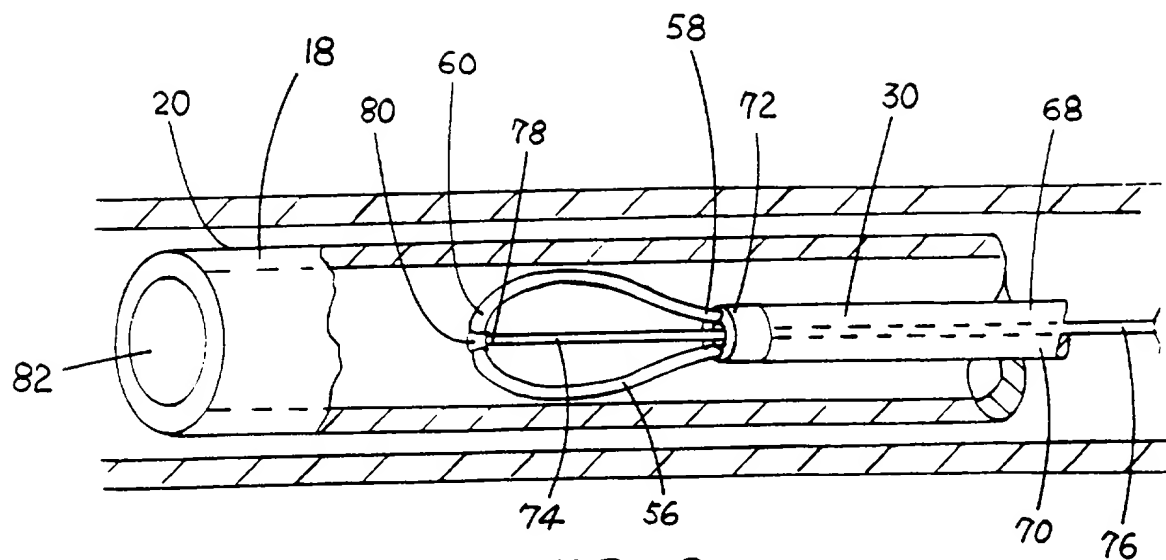


FIG. 8

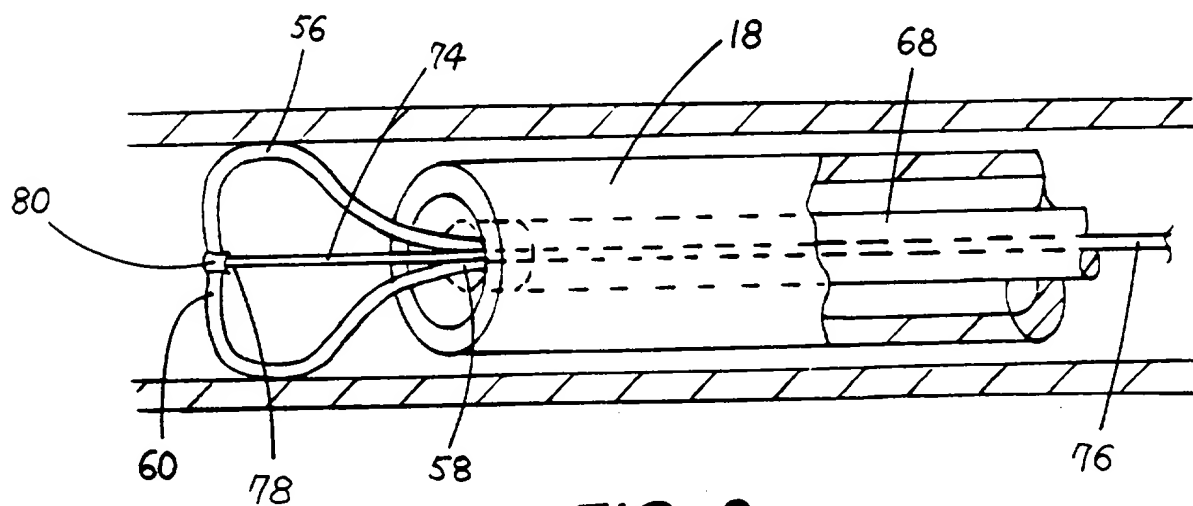


FIG. 9

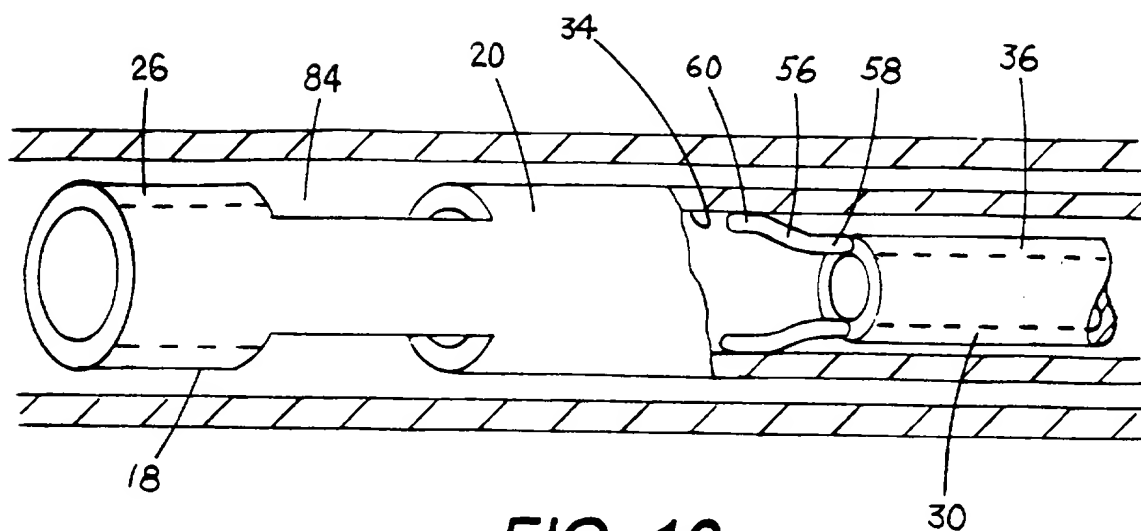


FIG. 10

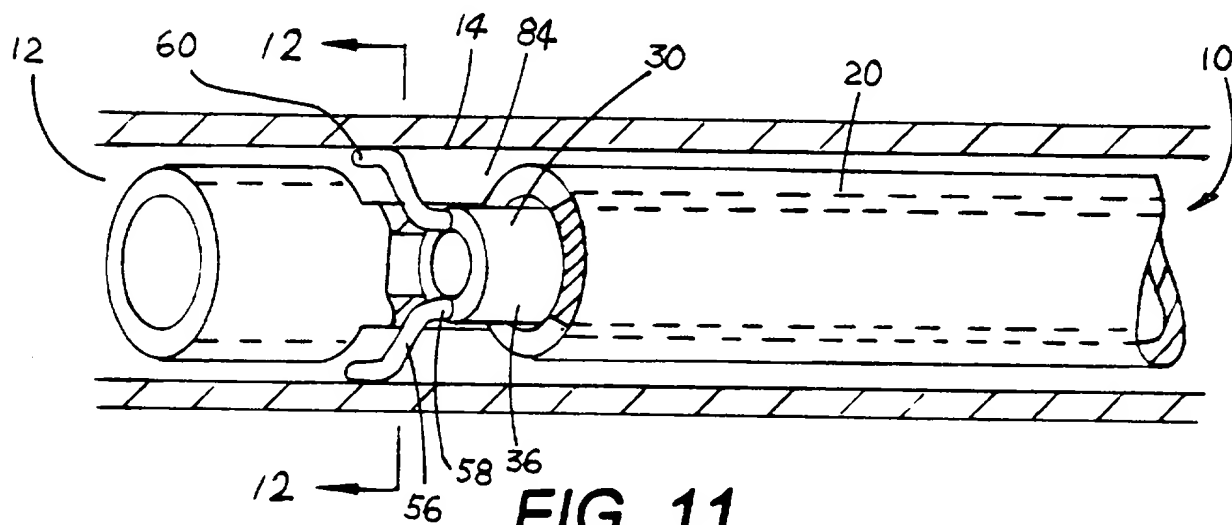


FIG. 11

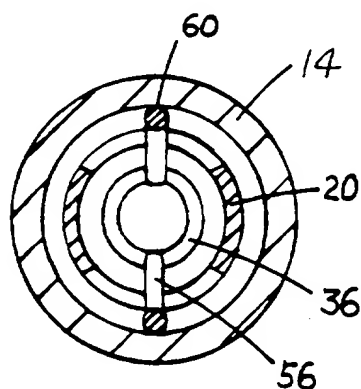


FIG. 12

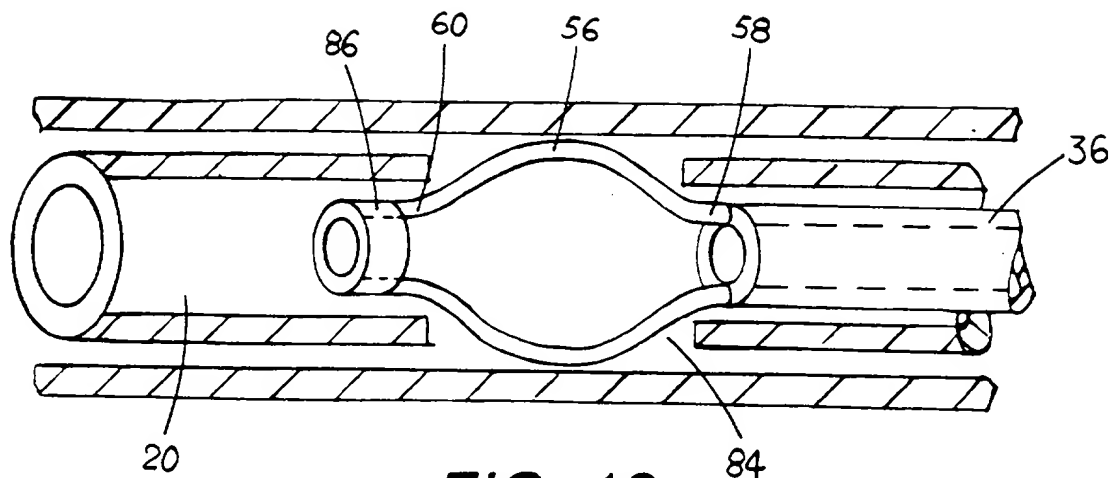


FIG. 13

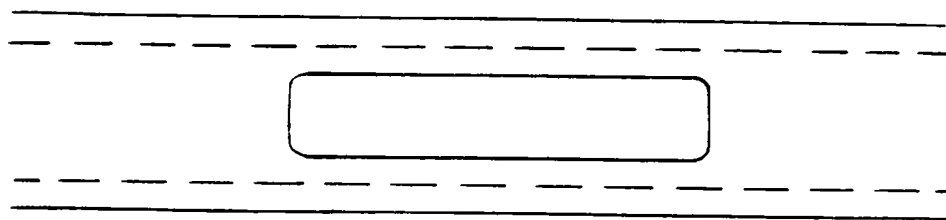


FIG. 14

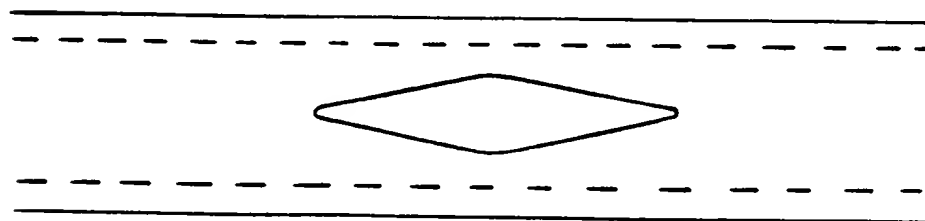


FIG. 15



FIG. 16

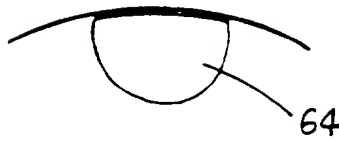


FIG. 17

SHELDON & MAKATTORNEY DOCKET NO.: 12032**United States Patent Application****COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **DEVICE FOR ANCHORING TUBULAR ELEMENT**

The specification of which

a. ☒ is attached hereto

b. ☐ was filed on _____ as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56 (see page 3 attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. ☒ no such applications have been filed.

b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

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I hereby claim the benefit under Title 35, United States Code, §120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Jeffrey G. Sheldon, Reg. No. 27,953; Denton L. Anderson, Reg. No. 30,153; David A. Farah, Reg. No. 38,134; Sol L. Goldstein, Reg. No. 20,376; Karin E. Peterka, Reg. No. 35,976; Harold R. Patton, Reg. No. 22,157; Reed A. Duthler, Reg. No. 30,626; Daniel W. Latham, Reg. No. 30,401; Michael B. Atlas, Reg. No. 30,606; Dianne M.F. Plunkett, Reg. No. 35,649; Michael J. Jaro, Reg. No. 34,472; Curtis D. Kinghorn, Reg. No. 33,926; Thomas F. Woods, Reg. No. 36,726; and Peter Forrest, Reg. No. 33,235.

I hereby authorize them to act and rely on instructions from and communication directly with the person/assignee/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Sheldon & Mak to the contrary.

Please direct all correspondence in this case to Sheldon & Mak at the address indicated below:

Sheldon & Mak
Attn: Karin E. Peterka
225 South Lake Avenue, 9th Floor
Pasadena, California 91101
Telephone No. (626) 796-4000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

201	FULL NAME OF INVENTOR	FIRST Name LEE	Middle Initial(s) M.	LAST Name MIDDLEMAN	
	RESIDENCE & CITIZENSHIP	City PORTOLA VALLEY	State or Foreign Country CALIFORNIA		Country of Citizenship UNITED STATES
	POST OFFICE ADDRESS	Post Office Address 16 COALMINE VIEW	City PORTOLA VALLEY	State or Country CALIFORNIA	Zip Code 94028
202	FULL NAME OF INVENTOR	FIRST Name WALTER	Middle Initial(s) R.	LAST Name PYKA	
	RESIDENCE & CITIZENSHIP	City REDWOOD CITY	State or Foreign Country CALIFORNIA		Country of Citizenship UNITED STATES
	POST OFFICE ADDRESS	Post Office Address P.O. BOX. 610023	City REDWOOD CITY	State or Country CALIFORNIA	Zip Code 94061
203	FULL NAME OF INVENTOR	FIRST Name	Middle Initial(s)	LAST Name	
	RESIDENCE & CITIZENSHIP	City	State or Foreign Country		Country of Citizenship
	POST OFFICE ADDRESS	Post Office Address	City	State or Country	Zip Code
Signature of Inventor 201		Signature of Inventor 202		Signature of Inventor 203	
Date July 23, 1998		Date		Date	

For Additional Inventors:

Indicate here and attach sheet with same information, including date and signature.

APPLICABLE STATUTES & RULES

37 C.F.R. § 1.56 - DUTY OF DISCLOSURE; FRAUD; STRIKING OR REJECTION OF APPLICATIONS

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

Information relating to the following factual situations enumerated in 35 U.S.C. § 102 and § 103 should be considered material under 37 C.F.R. § 1.56(a):

A person shall be entitled to a patent unless --

(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 103 - CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 119 - BENEFIT OF EARLIER FILING DATE IN FOREIGN COUNTRY; RIGHT OF PRIORITY (Applicable Portion)

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which has been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

35 U.S.C. § 120 - BENEFIT OF EARLIER FILING DATE IN THE UNITED STATES

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, by the same invention shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 112 - SPECIFICATION (Applicable Portion)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

SHELDON & MAKATTORNEY DOCKET NO.: 12032**United States Patent Application****COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **DEVICE FOR ANCHORING TUBULAR ELEMENT**

The specification of which

a. ☒ is attached hereto

b. ☐ was filed on _____ as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

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	POST OFFICE ADDRESS	Post Office Address P.O. BOX. 610023	City REDWOOD CITY	State or Country CALIFORNIA	Zip Code 94061	
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	RESIDENCE & CITIZENSHIP	City	State or Foreign Country		Country of Citizenship	
	POST OFFICE ADDRESS	Post Office Address	City	State or Country	Zip Code	
Signature of Inventor 201			Signature of Inventor 202 <i>Walter R. Pyka, cum</i>			Signature of Inventor 203
Date			Date 7/23/98			Date

For Additional Inventors:

__ Indicate here and attach sheet with same information, including date and signature.

APPLICABLE STATUTES & RULES

37 C.F.R. § 1.56 - DUTY OF DISCLOSURE; FRAUD; STRIKING OR REJECTION OF APPLICATIONS

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

Information relating to the following factual situations enumerated in 35 U.S.C. § 102 and § 103 should be considered material under 37 C.F.R. § 1.56(a):

A person shall be entitled to a patent unless --

(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 103 - CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 119 - BENEFIT OF EARLIER FILING DATE IN FOREIGN COUNTRY; RIGHT OF PRIORITY (Applicable Portion)

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which has been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

35 U.S.C. § 120 - BENEFIT OF EARLIER FILING DATE IN THE UNITED STATES

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, by the same invention shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 112 - SPECIFICATION (Applicable Portion)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.